**IC 25-26-16.5**

## Chapter 16.5. Drug Regimens in Health Facilities

**IC 25-26-16.5-1**

**Application**

Sec. 1. This chapter applies to a health facility licensed under IC 16-28.

*As added by P.L.75-2004, SEC.3.*

**IC 25-26-16.5-2**

**"Attending physician"**

Sec. 2. (a) As used in this chapter, "attending physician" means a physician licensed under IC 25-22.5 who is responsible for the ongoing health care of an individual who resides in a health facility.

(b) The medical director of a health facility to which the individual is admitted may not serve as the individual's attending physician unless the medical director meets the requirements set forth in subsection (a).

*As added by P.L.75-2004, SEC.3.*

**IC 25-26-16.5-3**

**"Protocol"**

Sec. 3. As used in this chapter, "protocol" means a policy, procedure, or protocol of a health facility concerning the adjustment of a patient's drug regimen as allowed under this chapter by a pharmacist licensed under this article.

*As added by P.L.75-2004, SEC.3.*

**IC 25-26-16.5-4**

**"Therapeutic alternative"**

Sec. 4. As used in this chapter, "therapeutic alternative" means a drug product that:

(1) has a different chemical structure from;

(2) is of the same pharmacological or therapeutic class as; and

(3) usually can be expected to have similar therapeutic effects and adverse reaction profiles when administered to patients in therapeutically equivalent doses as;

another drug.

*As added by P.L.75-2004, SEC.3.*

**IC 25-26-16.5-5**

**Adjustment of a drug regimen by a pharmacist**

Sec. 5. For purposes of this chapter, a pharmacist adjusts a drug regimen if the pharmacist:

(1) changes the duration of treatment for a current drug therapy;

(2) adjusts a drug's strength, dosage form, frequency of administration, or route of administration;

(3) discontinues the use of a drug; or

(4) adds a drug to the treatment regimen.

*As added by P.L.75-2004, SEC.3.*

**IC 25-26-16.5-6**

**Attending physician's duty to determine whether a protocol adopted by a hospital applies to a specific patient**

Sec. 6. At the time an individual is admitted to a health facility that has adopted a protocol under this chapter, the individual's attending physician shall signify in writing in the form and manner prescribed by the health facility whether the protocol applies in the care and treatment of the individual.

*As added by P.L.75-2004, SEC.3.*

**IC 25-26-16.5-7**

**Authority of a pharmacist to adjust a drug regimen**

Sec. 7. (a) A pharmacist may adjust the drug therapy regimen of the individual under:

(1) the written authorization of the individual's attending physician under section 6 of this chapter;

(2) the health facility's protocols; and

(3) this chapter.

(b) The pharmacist shall review the appropriate medical records of the individual to determine whether the attending physician has authorized the use of a specific protocol before the pharmacist adjusts the individual's drug therapy regimen.

(c) Notwithstanding subsection (a), if a protocol involves parenteral nutrition of the patient, the pharmacist shall communicate with the attending physician to receive approval to begin the protocol. The pharmacist shall document the authorization of the attending physician to use the protocol immediately in the individual's medical record.

*As added by P.L.75-2004, SEC.3.*

**IC 25-26-16.5-8**

**Drug regimen review committee**

Sec. 8. If a health facility elects to implement, revise, or renew a protocol under this chapter, the health facility shall establish a drug regimen review committee consisting of:

(1) the health facility's medical director;

(2) the health facility's director of nursing; and

(3) a consulting pharmacist licensed under this article;

for the implementation, revision, or renewal of a protocol.

*As added by P.L.75-2004, SEC.3.*

**IC 25-26-16.5-9**

**Modification of written protocol requires new protocol; exception**

Sec. 9. Except for the addition or deletion of authorized physicians and pharmacists, a modification to a written protocol requires the initiation of a new protocol.

*As added by P.L.75-2004, SEC.3.*

**IC 25-26-16.5-10**
**Basis and review of protocol**

Sec. 10. (a) A protocol of a health facility developed under this chapter must be:

(1) based on clinical considerations; and

(2) reviewed by the health facility's drug regimen committee at least quarterly.

(b) A protocol of a health facility developed under this chapter may not:

(1) prohibit the attending physician from approving only specific parts of a protocol; or

(2) provide for an adjustment to an individual's drug regimen for the sole purpose of achieving a higher reimbursement for the substituted drug therapy than what would have been received for the original drug therapy ordered by the attending physician.

*As added by P.L.75-2004, SEC.3.*

**IC 25-26-16.5-11**
**Required elements of a protocol**

Sec. 11. A protocol developed under this chapter must include the following:

(1) The identification of:

(A) the individual whose drug regimen may be adjusted;

(B) the attending physician who is delegating the authority to adjust an individual's drug regimen; and

(C) the pharmacist who is authorized to adjust the individual's drug regimen.

(2) The attending physician's diagnosis of the individual's:

(A) condition; or

(B) disease state;

whose drug regimen may be adjusted.

(3) A statement regarding:

(A) the types and:

(i) categories; or

(ii) therapeutic classifications;

of medication, including the specific therapeutic alternatives that may be substituted for a drug prescribed by a physician;

(B) the minimum and maximum dosage levels within the types and:

(i) categories; or

(ii) therapeutic classifications;

of medications described in clause (A);

(C) the dosage forms;

(D) the frequency of administration;

(E) the route of administration;

(F) the duration of the administration of the drug regimen and any adjustment to the drug regimen; and

(G) exceptions to the application of the drug regimen or the adjustment to the drug regimen;

for which the pharmacist may adjust the individual's drug regimen.

(4) A requirement that:

(A) the individual's medical records be available to both the individual's attending physician and the pharmacist; and

(B) the procedures performed by the pharmacist relate to a disease or condition for which the patient has been under the attending physician's medical care.

*As added by P.L.75-2004, SEC.3.*

**IC 25-26-16.5-12**

**Protocol must comply with certain Medicaid requirements**

Sec. 12. A protocol developed under this chapter that is implemented for a Medicaid recipient must comply with any statutes, regulations, and procedures under the state Medicaid program relating to the preferred drug list established under IC 12-15-35-28.

*As added by P.L.75-2004, SEC.3.*

**IC 25-26-16.5-13**

**Duration of authorization of therapeutic alternative**

Sec. 13. If a protocol developed under this chapter allows a pharmacist to substitute a therapeutic alternative for the drug prescribed by the individual's attending physician, the attending physician's authorization of the substitution is valid only for the duration of the prescription or drug order.

*As added by P.L.75-2004, SEC.3.*

**IC 25-26-16.5-14**

**Unauthorized therapeutic alternatives prohibited**

Sec. 14. This chapter does not allow a pharmacist to substitute a therapeutic alternative for the drug prescribed by the individual's attending physician unless the substitution is authorized by the attending physician under a valid protocol under this chapter.

*As added by P.L.75-2004, SEC.3.*

**IC 25-26-16.5-15**

**Attending physician's duty to review an implemented protocol**

Sec. 15. The individual's attending physician:

(1) shall review a protocol approved and implemented for a patient of the physician at the physician's next visit to the health facility, and at each subsequent visit of the physician to the health facility; and

(2) may at any time modify or cancel a protocol by entering the modification or cancellation in the individual's medical record.

*As added by P.L.75-2004, SEC.3.*

**IC 25-26-16.5-16**

**Protocol documentation required**

Sec. 16. (a) Documentation of protocols must be maintained in a current, consistent, and readily retrievable manner.

(b) After making an adjustment to an individual's drug regimen, the pharmacist shall immediately document the adjustment in the patient's medical record.

(c) The pharmacist shall notify the individual's attending physician of an adjustment at least one (1) business day before the adjustment is made.

*As added by P.L.75-2004, SEC.3.*

**IC 25-26-16.5-17**

**Confidentiality; liability**

Sec. 17. (a) This chapter does not modify the requirements of other statutes relating to the confidentiality of medical records.

(b) This chapter does not make any other licensed health care provider or pharmaceutical manufacturer liable for the actions of a pharmacist carried out under this section.

(c) A physician who approves the use of a protocol under this chapter and a pharmacist who adjusts a drug regimen of a patient pursuant to a protocol under this chapter do not violate IC 25-22.5-1-2(d).

*As added by P.L.75-2004, SEC.3.*

**IC 25-26-16.5-18**

**Pharmacist subject to discipline for violations**

Sec. 18. A pharmacist who violates this chapter is subject to discipline under IC 25-1-9.

*As added by P.L.75-2004, SEC.3.*